510(k) Premarket Notification

K033736

Panel Packet

Concentric MERCI® Retriever

Concentric Medical, Inc.
1380 Shorebird Way
Mountain View, CA 94043

4022B1-510K PREMARKET NOT.

Indications for Use

510(k) Number (if known):	This application
Device Name:	Concentric MERCI Retriever
Indications for Use:	The MERCI Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing an ischemic stroke. The MERCI Retriever is also indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vascular systems.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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ADMINISTRATIVE INFORMATION

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Establishment Registration Number

2954917

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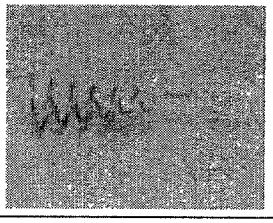
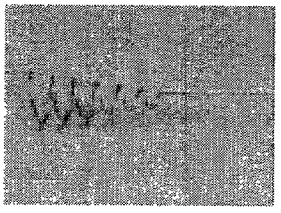
1721676

DEVICE OVERVIEW

The MERCI Retriever consists of a flexible, tapered core wire with helical loops at the distal end. A platinum coil at the distal end allows fluoroscopic visualization. Retriever dimensions are indicated on the product label. The Retriever has a hydrophilic coating to reduce friction during use. A torque device is provided with the Retriever to facilitate manipulation. The torque device is marked to facilitate counting the number of revolutions. An insertion tool is provided to introduce the Retriever into a microcatheter.

The MERCI Retriever is available in two configurations, MERCI Retriever X5 and MERCI Retriever X6. Table 1 describes the differences between the two configurations.

Table 1
Comparison of MERCI Retriever X5 and MERCI Retriever X6

Geometric Attribute	MERCI Retriever X5	MERCI Retriever X6
Distal Tip Corewire		
Number of Loops	5	5
Loop Core wire Diameter	0.0040"	0.0050"
Distal Tip Core wire Diameter	0.0026"	0.0026"
Distal Loop Diameter	1.1mm	1.1mm
Proximal Loop Diameter	2.7mm	2.7mm
Loop Length	7mm	7mm
Tip Length	7mm	7mm
Maximum Outer Diameter	0.012"	0.014"
Useable Length	180cm	180cm

Note: All dimensions are nominal unless otherwise stated.

Principle of Operation
The detailed operating instructions may be found in the Instructions for Use in Attachment A. The following is a summary of the procedure.

Using standard catheterization technique, the MERCI Balloon Guide Catheter and dilator are tracked over an indwelling guidewire to the targeted vessel. The guidewire and dilator are removed allowing the operator to inject contrast media to visualize the vessel and target treatment site.

A guidewire contained within a microcatheter is inserted and advanced through the Balloon Guide Catheter to the location of the occlusion. The guidewire and microcatheter are advanced beyond the occlusion. To visualize the vasculature beyond the occlusion, the guidewire is removed and contrast is injected through the microcatheter.

With the distal end of the microcatheter beyond the occlusion, the MERCI Retriever is inserted into the microcatheter. The MERCI Retriever is advanced through the microcatheter until the helix exits the tip of the microcatheter and ensnares the clot.

Prior to moving the clot within the vessel, the Balloon Guide Catheter is inflated to control blood flow. The MERCI Retriever with the ensnared clot and the microcatheter are then withdrawn together into the Balloon Guide Catheter. During withdrawal of the thrombus into the guide catheter, continuous aspiration is applied to the MERCI Balloon Guide Catheter to ensure complete thrombus removal. Upon confirmation of complete evacuation of thrombus from the Balloon Guide Catheter, the balloon is deflated and a final angiogram is performed to confirm revascularization at the treatment site.

RETRIEVER FRACTURE ANALYSIS

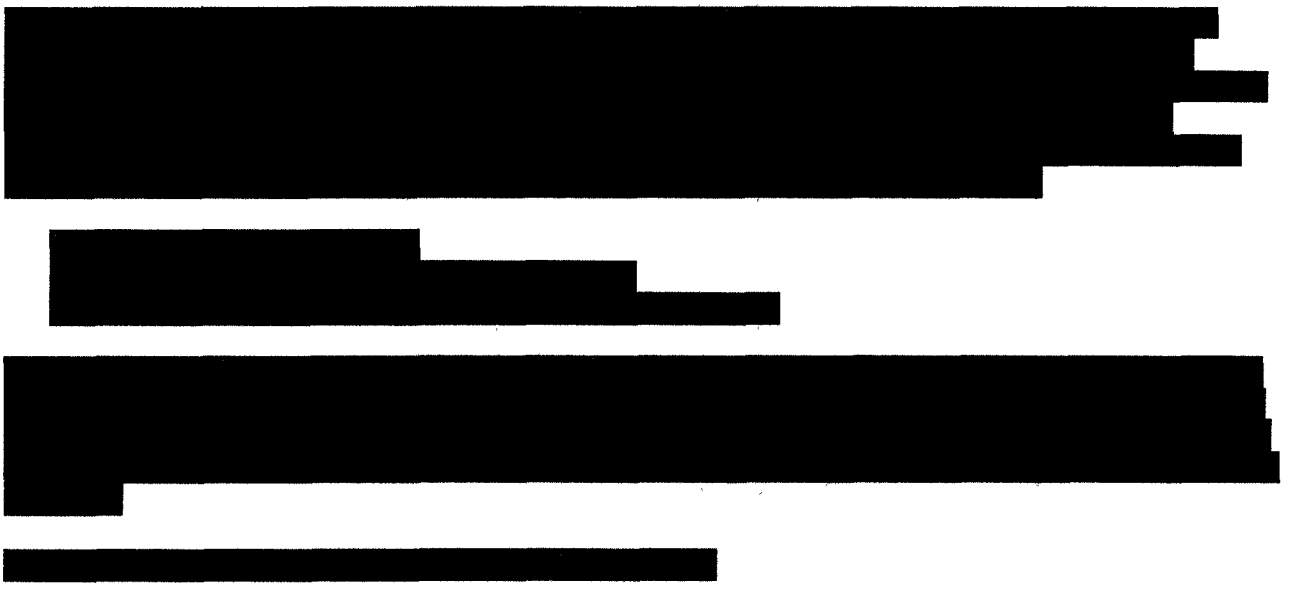


Figure 1 – Patient Outcome

[redacted]

Figure 2 – [redacted]

[redacted]

Table 2 details the procedure specifics and patient outcomes in which a device detached and who were not reported in the MERCI Clinical Summary.

Table 2
Device Fractures at Time of 510(k) Submission

Pt. ID	Complaint	Patient Outcome	Failure Investigation	Corrective/Preventive Action
[redacted]				
[redacted]				
[redacted]				
[redacted]				

INSTRUCTIONS FOR USE AND DEVICE LABELING

To minimize the risk of tip fracture, the Instructions for Use have been amended to include specific warnings against over torquing of the MERCI Retriever and to provide awareness that device fractures have been observed during the MERCI Clinical Trial. A draft of the Instructions for Use and device label have been provided in Attachment A.

MERCI CLINICAL TRIAL OVERVIEW

The clinical objective of the MERCI Clinical Investigation was to establish in patients experiencing an ischemic stroke whether the MERCI Retriever could access an occluded intracerebral vessel, remove the occlusion and restore blood flow while minimizing vessel damage and distal embolization.

In the MERCI study, the treatable vessels included the middle cerebral (M1/M2 segment), internal carotid, basilar and vertebral arteries. Successful revascularization was defined as the achievement of blood flow (TIMI II/III Flow) following treatment with the MERCI Retriever.

Safety was assessed by an independent data safety monitoring board (DSMB) who reviewed and adjudicated all serious adverse events (SAE). The DSMB met regularly to review the specifics of each serious adverse event and they made a determination of whether or not the SAE was related to the device, procedure and/or evolution of the stroke. As described in the MERCI Phase II protocol, all serious adverse events were categorized as one of the following: "Definitely Device Related", "Probably Device Related", "Possibly Device Related", and "Unlikely Related to the Device". The serious device-related adverse event rate was computed based on all events that were "Definitely", "Probably" or "Possibly" device related. After each analysis of the device-related SAE rate, the DSMB determined whether to continue with patient enrollment.

In total, there were four serious device-related adverse events. Two patients experienced a subarachnoid hemorrhage during or immediately post procedure and the investigators and DSMB indicated that both hemorrhages were "Possibly" related to the MERCI Retriever. One patient was treated with balloon angioplasty, a Microvena Snare and a Guidant Neuronet foreign body retrieval device following treatment with the MERCI Retriever all of which could be implicated as the cause of the hemorrhage. The second patient was treated with only the MERCI Retriever. The remaining two patients experienced thrombus embolization of the anterior cerebral artery following successful revascularization of the middle cerebral artery. Specific details on all serious adverse events are reported in the MERCI Clinical Report – Table 17 and 18.

Vessel revascularization was defined as achievement of at least TIMI Grade II blood flow in all the major treatable vessels within the affected territory post treatment with the MERCI Retriever. Treatable vessels as defined by the MERCI Phase II protocol are detailed in **Table 3**.

Table 3
Treatable Vessels/Territory

Territory	Cerebral Artery
Anterior Circulation	Internal Carotid Middle Cerebral (M1/M2 segments)
Posterior Circulation	Basilar Vertebral

Restoration of TIMI II/III flow in all the major vessels was achieved in 54% (61/114) of the patients treated. The Phase II protocol states that the successful revascularization rate for the MERCI Retriever

must be statistically different than the 18% recanalization rate experienced by the placebo group in the PROACT II study. The probability (i.e., p-value) for a study with 114 patients having 61 or more "successes" given the underlying probability of an 18% success rate is < 0.0001[1].

In addition, the MERCI Phase II protocol established a primary endpoint of a minimum recanalization rate of 30% following treatment with the MERCI Retriever. The probability (i.e., p-value) for a study with 114 patients having 61 or more "successes" given the underlying probability of a 30% success rate is < 0.0001[1]. These data are summarized in **Table 4**.

Table 4
MERCI Results

Successful Revascularization	Serious Device-Related Adverse Events
54% (61/114) p<0.0001[1]	3.5% (4/114)

The successful revascularization rate and low incidence of serious device-related adverse events achieved in the MERCI Clinical Trial support the benefits of using the MERCI Retriever for the removal of neurovascular thrombus in patients experiencing ischemic stroke. Effectiveness data presented within the MERCI Clinical Summary further demonstrate that successful revascularization correlates to improved patient outcomes. As a result, the risk of vessel perforation, dissection, and embolization while removing thrombus with the MERCI Retriever are appropriate in light of the demonstrated clinical benefit.

In conclusion, the clinical performance data demonstrate that the MERCI Retriever is safe and effective for its intended use. A complete clinical summary may be found in Attachment B.

[1] Exact Binomial Test